

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
6 May 2004 (06.05.2004)

PCT

(10) International Publication Number
WO 2004/037263 A1

(51) International Patent Classification⁷: **A61K 31/522**,
A61P 31/12, 31/22

Thane (West), 400601 Mumbai, Maharashtra (IN). **MA-
LIK, Rajiv** [IN/AT]; Haus 13/4, Unterer Schreiberweg,
A-1190 Wien (AT).

(21) International Application Number:
PCT/IB2003/004664

(22) International Filing Date: 22 October 2003 (22.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1058/DEL/2002 22 October 2002 (22.10.2002) IN

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(71) Applicant (*for all designated States except US*): **RAN-
BAXY LABORATORIES LIMITED** [IN/IN]; 19, Nehru
Place, 110019 New Delhi, Delhi (IN).

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **MATHUR, Rajeev**,
Shankar [IN/IN]; KD-66, Ashok Vihar Phase - 1, 110052
Delhi, Delhi (IN). **KUMAR, Pananchukunnath, Manoj**
[IN/IN]; 25 Laxmi Vihar Apartments, Block H-3, Vikas
Puri, 110018 New Delhi, Delhi (IN). **ROY, Sunilendu**,
Bhushan [IN/IN]; Bungalow # 7, Row House, Lokpuram,

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITIONS OF GANCICLOVIR

(57) **Abstract:** The technical field of the invention relates to pharmaceutical compositions of 9-(1,3-dihydroxy-2-propoxymethyl) guanine (ganciclovir) that are stable and contain more than 1% water content. One pharmaceutical composition includes ganciclovir having more than about 1% water content, and one or more pharmaceutically acceptable excipients. The ganciclovir retains at least about 97% of its initial purity after one month, at least about 96% of its initial purity after two months, and at least about 95% of its initial purity after three months when stored at 40°C and 75% RH. In particular, the water content may be between about 2% and about 6%.

WO 2004/037263 A1